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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/692,314	08/05/96	HAMLIN	R 910458.CDA

EXAMINER

13M1/1114

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MAKLS
ART UNIT PAPER NUMBER

1301

DATE MAILED: 11/14/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7-31-97 and 6-18-97

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 116, 118-125, 127, 128, 130-134, 136-143, 145-146, 148-165 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 116, 118-125, 127, 128, 130-134, 136-143, 145-146, 148-165 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Interview Summary, PTO-413 (Paper # 38 1/2)
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

TEST AVAILABLE COPY

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1) The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

2) Claims 116, 118-125, 127-128, 131-134, 136-143, 145-146 and 149-161 and 162-165 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Japan '463 (JA 58-188463), "Coextruded composite film" by Parker, Patel and optionally further in view of Dyke and /or Japan '353 (JA 53-45353).

Levy, directed to a balloon for a catheter, discloses extruding a tube of polyethylene terephthalate, heating the tube and drawing the tube and inflating the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm). At col 4 lines 45-50, Levy discloses fabricating the

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balloon catheter comprising the balloon by means of conventional techniques.

Japan '463 shows a balloon secured at each end to a catheter tube wherein the balloon comprises two layers 13 and 14 with layer 14 being provided on layer 13. See abstract, figures. During an oral translation of Japan '463 by a PTO translator, the following information was obtained: Japan '463 discloses that layer 14 is a gas penetration layer which was formed by coating over a soft plastic film 13. Japan '463, which lists a variety of materials which can be used for layer 13, also teaches that layer 14 can be provided on the inside surface of layer 13. See translation provided by applicant.

Parker, directed to coextruded composite film, teaches bringing a first layer and second layer of polymers into contact in a single die while they are still in a molten state, extruding the layers from the die to form a tube and inflating the tube with air to stretch the tube to a desired thickness. Parker teaches bonding takes place inside the extruder die head and the film leaves the die as a completely multilayered structure. Parker et al teaches that by providing the second layer a "good sealing film" having the all the desired properties of the first layer can be obtained. Parker specifically discloses: "All

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coextruded films offer freedom from pinholes; it is virtually impossible for a pinhole in one film layer to line up with a pinhole which exists in another film." Parker lists "[a]dhesion to other substrates with or without adhesives" as being one of the "property advantages offered by specially tailored coextruded composite films"

As to independent claims 116, 134 and 152 and dependent claims 133, 151, and 165, it would have been obvious to:

(i) coextrude two different polymeric materials so as to form a two layer tubing; and

(ii) use the two layer tubing in the Levy process which as noted above includes steps of heating the tube, drawing the tube and radially expanding the tube in a blow molding fixture to form the balloon such that the resulting balloon is sized and configured for intravascular coronary angioplasty use, has a burst pressure in excess of seven atmospheres, and the first balloon layer has a greater burst strength than the second balloon layer,

SINCE:

(a) Levy teaches extruding plastic material to form a tubing which is to be used to form a balloon;

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(b) Japan '463 teaches forming a two layer balloon for the advantage of making the balloon more gas impermeable;

(c) Parker suggests coextruding a low melting point plastic material with a high melting point plastic material in order to form a two layer tube which is virtually free from pinholes; and

(d) the use of coextrusion to form tubing is known per se in the balloon catheter art for the purpose of improving bonding as shown by Patel

AND OPTIONALLY SINCE:

(e) Japan '353 shows the use of coextrusion and biaxial orientation is known per se.

Hence, the prior art as a whole suggests/motivates forming a two layer balloon by the known technique of coextrusion in order to improve the impermeability (Japan '463/Parker) and adherability (Parker/Patel/Japan '353) of a high burst pressure balloon formed by the process of Levy.

Although no longer claimed, the following conclusion is made: It would have been obvious to one of ordinary skill in the art to attach the balloon to a catheter by using melt bonding since (a) Levy suggests fabricating a balloon catheter by a conventional technique which one of ordinary skill in the art would readily understand as including a step of attaching the

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balloon to a catheter, (b) Patel teaches attaching a balloon to a catheter tube by using an adhesive or by heat sealing and (c) Dyke which shows that it is well known in the catheter art to attach a balloon, which has a second material on its inner surface, to a catheter tube using melt bonding of the second material. Dyke, therefore, constitutes additional suggestion to coextrude two layers and use such layers in the Levy process of forming a high burst pressure balloon - the suggestion being provision of a second material on the inner surface of the balloon to allow heat sealing of the balloon to a catheter; it being noted again that coextrusion of two layers, one of which is heat sealable, is taught by Patel as being a technique known to those in the balloon catheter art.

The limitation of the material of the outer layer and the material of the inner layer and the outer layer as set forth in claims 118-125, 127-128, 131-132, 136-143, 145-146, 149-150, 153-161, 163-164 would have been obvious in view of (a) the above noted suggestion from the secondary references to form a two layer balloon, (b) Levy's al's teaching that the biaxially oriented material of a layer of a balloon may be a polymer such as polyethylene terephthalate and (c) well known polymeric material for a layer of a balloon include polymeric material such

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as polyvinyl chloride, polyurethane and polyethylene as evidenced by Levy (column 1) and Patel (column 1). With respect to the inner layer being polyethylene, one of ordinary skill in the art would readily recognize from Parker/ Japan '353 that polyethylene would improve the heat sealability of the balloon. With respect to the claims directed to two different polyester materials, the use of two different polyester materials as set forth therein would have been obvious (a) the above noted suggestion from the secondary references to form a two layer balloon, (b) Levy's al's teaching that the biaxially oriented material of a layer of a balloon may be a polymer such as polyethylene terephthalate and (c) polyester having a relatively low crystallinity is taken as a well known heat sealable material per se in the bonding art.

3) Claims 130, 148 and 162 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Japan '463, Parker, Patel and optionally further in view of Dyke and /or Japan '353 as applied above and further in view of Merrill and Lambert.

Levy does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

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Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claims 130, 148 and 162, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic so that advantageously the outer polymeric surface of the balloon catheter will have a low coefficient of friction when wet since (a) Levy teaches fabricating a catheter comprising the balloon and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

4)

REMARKS

Applicant's arguments with respect to claims 116, 118-125, 127-128, 130-134, 136-143, 148-165 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 6-18-97 and 7-31-97 have been fully considered but they are not persuasive.

Wang et al US Patent 5,195,969 filed 4-26-91 is not available as prior art under 35 USC 102 against pending claims

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116, 118-125, 127-128, 130-134, 136-143, 145-146, 148-165 since each of these claims is directed solely to subject matter disclosed in and entitled to the benefit of the filing date of 07/411,649 filed 9-25-89.

Applicant's argument that Levy does not teach or suggest a method of making a catheter balloon comprising co-extruding a tube having a first layer comprising a first polymeric material and a second layer comprising a second polymeric material which is different than the first polymeric material is not persuasive since the secondary art provides the suggestion / motivation to modify the process of Levy so as to use a co-extruded tube having a first layer comprising a first polymeric material and a second layer comprising a second polymeric material which is different than the first polymeric material to form the balloon INSTEAD OF using a single layer tube of one composition to form the balloon.

With respect to the PTO 1449 filed 11-14-96 and the PTO 1449 filed 5-20-97, the references crossed off have already been cited on either a PTO 1449 or a PTO 892 with two exceptions: Japan 2255027 and Japan 6221. However, the Opposition Statement (cited by applicant) which discusses Japan 2255027 and has the number 6221 thereon has been considered.

5) No claim is allowed.

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6) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (703) 308-2068. The examiner can normally be reached on Monday to Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball, can be reached on (703)

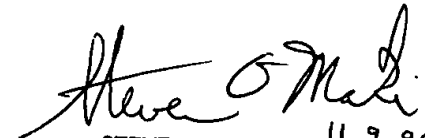
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308-2058. The fax phone number for Art Unit 1301 is (703) 305-7115. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0651.

Steven D. Maki
November 9, 1997


STEVEN D. MAKI 11-9-97
PRIMARY EXAMINER
GROUP 1300